



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/117,823	11/09/87	ZICGIOTTI	A RWP24471

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EXAMINER	
NORTHINGTON, Z	
ART UNIT	PAPER NUMBER
121	8

DATE MAILED:

10/24/88

10/24/88

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on July 11, 1988 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-11 are pending in the application.
Of the above, ~~claims~~ none are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-11 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Art Unit 121

The text of those sections of Title 35 U. S. Code not included in this action can be found in a prior Office action.

Claims 2-7 are rejected under 35 U.S.C. 103 as being unpatentable over Sallmann et al.

The instantly claimed process for preparing a soluble salt is disclosed by Sallmann et al. Sallmann et al. teach the reaction which 1) dissolves the diclofenac in an organic solvent; 2) adds a base; 3) reacts said compounds together; 4) removes the solvent by distillation; and 5) crystallizes the product obtained. See Column 10, lines 39-58, respectively.

There are no reaction conditions of temperature and pressure recited in the independent claim and no manipulative steps are claimed other than what are embodied in the word reacting. Results obtained by the reaction are expected and obvious therefrom, since only the predicted reaction takes place. See In re Albertson, 141 USPQ 730.

Claims 1 and 8-11 are rejected under 35 U.S.C. 103 as being unpatentable over Sallmann et al.

Note reasons of record at Paper No. 3.

Claim 8 is again rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The said claim is non-limiting by the recitation of the term "containing" which implies a composition with other ingredients which are not specified.

Art Unit 121

RESPONSE TO APPLICANT'S REMARKS

Applicants state Sallmann et al. merely disclose pharmaceutically acceptable salts derived from a laundry list of nontoxic inorganic and organic bases, and disclose that the diclofenac compound may be administered in various dosage forms such as tablets, powders, suspensions and solutions.

There is no teaching that the claimed cyclic organic bases will react with diclofenac to form salts which are water soluble.

Again, Sallmann et al. discloses pharmaceutical acceptable salts such as sodium, potassium, pyrrolidine, morpholine, or 2-piperidino-ethanol that the diclofenac compound may be administered in various forms. Ampoules for parenteral administration is another dosage form which is listed at Column 3, lines 66-74, respectively. The daily dosages which are taken internally consists of the diclofenac compound or a pharmaceutically acceptable salt thereof with a base. At Column 24, lines 34-39, parenteral administration such as ampoules preferably contain a water soluble salt. Therefore, Sallmann et al, disclose the instantly claimed water soluble salt of diclofenac.

Applicant's arguments filed July 11, 1988 have been fully considered but they are not deemed to be persuasive.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP 706.07(a).

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Art Unit 121

Applicant is reminded of the extension of time policy set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Zinna Northington whose telephone number is (703) 557-1230.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3920.

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9-29-88;df

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GRANT C. LEE
SUPERVISORY PRIMARY EXAMINER
ART UNIT 121